

Message

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**From:** Keigwin, Richard [Keigwin.Richard@epa.gov]  
**Sent:** 10/2/2017 10:01:32 PM  
**To:** Strauss, Linda [Strauss.Linda@epa.gov]  
**CC:** Beck, Nancy [Beck.Nancy@epa.gov]; Wise, Louise [Wise.Louise@epa.gov]  
**Subject:** Re: Genetically Engineered Mosquitos regulatory responsibility from FDA to EPA -- announcement expected this week

I agree it would need to be a joint release. The uses, though, that FDA would retain would also involve releases to the environment, so I don't think that thread is necessarily workable.

Rick Keigwin  
Director, Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Phone: 703-305-7090  
Website: [www.epa.gov/pesticides](http://www.epa.gov/pesticides)  
Sent from my iPhone

On Oct 2, 2017, at 5:53 PM, Strauss, Linda <[Strauss.Linda@epa.gov](mailto:Strauss.Linda@epa.gov)> wrote:

## Ex. 5 - Deliberative Process

Thanks.  
Sent from my iPhone

Begin forwarded message:

**From:** "Strauss, Linda" <[Strauss.Linda@epa.gov](mailto:Strauss.Linda@epa.gov)>  
**Date:** October 2, 2017 at 5:14:17 PM EDT  
**To:** "Beck, Nancy" <[beck.nancy@epa.gov](mailto:beck.nancy@epa.gov)>, "Wise, Louise" <[Wise.Louise@epa.gov](mailto:Wise.Louise@epa.gov)>  
**Subject:** FW: Genetically Engineered Mosquitos regulatory responsibility from FDA to EPA -- announcement expected this week

Checking with others too.

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**From:** Strauss, Linda  
**Sent:** Monday, October 02, 2017 5:14 PM  
**To:** Grantham, Nancy <[Grantham.Nancy@epa.gov](mailto:Grantham.Nancy@epa.gov)>  
**Subject:** RE: Genetically Engineered Mosquitos regulatory responsibility from FDA to EPA -- announcement expected this week

Here's what I think.

1. <!--[if !supportLists]--><!--[endif]-->It would have to be a joint press release with FDA since they have the lead with the document. It would be FDA and EPA are announcing that approval is being transferred from FDA to EPA.
2. <!--[if !supportLists]--><!--[endif]-->The public and stakeholders don't care what Agency has the lead – it's all government. So obviously we would

have to say how what we're doing will make something better and FDA would have to agree to it:

## Ex. 5 - Deliberative Process

Attached is the listserv that FDA was planning to send and that we would also send on WEDNESDAY.

Linda

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**From:** Grantham, Nancy  
**Sent:** Monday, October 02, 2017 4:24 PM  
**To:** Strauss, Linda <[Strauss.Linda@epa.gov](mailto:Strauss.Linda@epa.gov)>  
**Subject:** FW: Genetically Engineered Mosquitos regulatory responsibility from FDA to EPA -- announcement expected this week

See below – will you check with others in ocspp re: press release ?

Thanks ng

**Nancy Grantham**  
**Office of Public Affairs**  
**US Environmental Protection Agency**  
**202-564-6879 (desk)**  
**202-253-7056 (mobile)**

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**From:** Graham, Amy  
**Sent:** Monday, October 02, 2017 4:18 PM  
**To:** Grantham, Nancy <[Grantham.Nancy@epa.gov](mailto:Grantham.Nancy@epa.gov)>; Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)>; Wilcox, Jahan <[wilcox.jahan@epa.gov](mailto:wilcox.jahan@epa.gov)>; Ferguson, Lincoln <[ferguson.lincoln@epa.gov](mailto:ferguson.lincoln@epa.gov)>; Hewitt, James <[hewitt.james@epa.gov](mailto:hewitt.james@epa.gov)>; Abboud, Michael <[abboud.michael@epa.gov](mailto:abboud.michael@epa.gov)>; Konkus, John <[konkus.john@epa.gov](mailto:konkus.john@epa.gov)>  
**Subject:** RE: Genetically Engineered Mosquitos regulatory responsibility from FDA to EPA -- announcement expected this week

This is a big deal – are we amplifying with a press release? I don't think we want a listserv being the first announcement of this do we?

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**From:** Grantham, Nancy  
**Sent:** Monday, October 2, 2017 4:01 PM

**To:** Bowman, Liz <Bowman.Liz@epa.gov>; Graham, Amy <graham.amy@epa.gov>;  
Wilcox, Jahan <wilcox.jahan@epa.gov>; Ferguson, Lincoln <ferguson.lincoln@epa.gov>;  
Hewitt, James <hewitt.james@epa.gov>; Abboud, Michael <abboud.michael@epa.gov>;  
Konkus, John <konkus.john@epa.gov>  
**Cc:** Grantham, Nancy <Grantham.Nancy@epa.gov>  
**Subject:** Genetically Engineered Mosquitos regulatory responsibility from FDA to EPA --  
announcement expected this week

**FYI – on this regulatory responsibility transferring from FDA to EPA – as  
genetically engineered mosquitos are considered pesticides.**

**Nancy Beck is looped in on this. FDA will issue a listserv which we will amplify  
(attached)**

**See background and Q and A below.**

**Thanks ng**

**Background for EPA Internal Use**

## **Ex. 5 - Deliberative Process**

**Back-Pocket Qs and As**

**Why would EPA now regulate a GE mosquito used for population control?**

## Ex. 5 - Deliberative Process

Why is the question of which agency will regulate GE mosquitoes being addressed at this time as part of the Coordinated Framework Update effort?  
Why not when companies first indicated they were developing GE mosquitoes?

## Ex. 5 - Deliberative Process

How does EPA regulate pesticides?

## Ex. 5 - Deliberative Process

Does USDA play a role in the regulation of insects?

## Ex. 5 - Deliberative Process

How do *Wolbachia* mosquitoes currently being regulated by EPA for population control differ from the GE mosquito?

The *Wolbachia* products currently before EPA are not GE mosquitoes. Rather they are infected with bacteria, called *Wolbachia pipientis*, that can affect the viability of the mosquito's eggs. The Oxitec GE mosquito is genetically engineered in such a way that the mosquito larvae cannot grow into mature adults in the environment. Both approaches are intended to control mosquito populations by preventing successful reproduction, but accomplish this in different ways. Both focus on making changes to male mosquitoes that would then be released into the wild to mate with "wild" female mosquitoes. The Oxitec mosquito is genetically engineered; the *Wolbachia*-infected mosquito is not. Only the female mosquitoes bite humans; male mosquitoes feed on flower nectar.

How did it happen that one product intended to lower the number of mosquitoes in the environment is currently being reviewed by EPA as a pesticide, while another mosquito product that is also intended to lower the mosquito population, up until this action, has been reviewed by FDA?

## **Ex. 5 - Deliberative Process**

Why do we need these mosquito products when chemical pesticides can be used to kill mosquitoes?

## **Ex. 5 - Deliberative Process**

If the GE mosquito had gone to EPA first, would it already have a final determination?

## **Ex. 5 - Deliberative Process**

How does this realignment of regulatory responsibility affect the potential use of these mosquitoes in countering the Zika outbreak in the United States?

## **Ex. 5 - Deliberative Process**

What does this mean for the developer of a GE mosquito, Oxitec, whose product is currently under review at FDA? Does this mean that Oxitec will have to go through additional review at EPA?

# Ex. 5 Deliberative Process (DP)

**Nancy Grantham**  
**Office of Public Affairs**  
**US Environmental Protection Agency**  
**202-564-6879 (desk)**  
**202-253-7056 (mobile)**

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**From:** Strauss, Linda  
**Sent:** Friday, September 29, 2017 12:48 PM  
**To:** Grantham, Nancy <[Grantham.Nancy@epa.gov](mailto:Grantham.Nancy@epa.gov)>  
**Subject:** FW: GE Mosquito Final Guidance Announcement

The exact timing of the FDA announcement next week is "still being determined." Attached is their listserv and Q/A's.

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**From:** Strauss, Linda  
**Sent:** Friday, September 29, 2017 12:46 PM  
**To:** Keigwin, Richard <[Keigwin.Richard@epa.gov](mailto:Keigwin.Richard@epa.gov)>; McNally, Robert <[McNally.Robert@epa.gov](mailto:McNally.Robert@epa.gov)>; Mendelsohn, Mike <[Mendelsohn.Mike@epa.gov](mailto:Mendelsohn.Mike@epa.gov)>; Milewski, Elizabeth <[Milewski.Elizabeth@epa.gov](mailto:Milewski.Elizabeth@epa.gov)>; Sisco, Debby <[Sisco.Debby@epa.gov](mailto:Sisco.Debby@epa.gov)>; Dinkins, Darlene <[Dinkins.Darlene@epa.gov](mailto:Dinkins.Darlene@epa.gov)>; Overstreet, Anne <[overstreet.anne@epa.gov](mailto:overstreet.anne@epa.gov)>; Lantz, Tracy <[Lantz.Tracy@epa.gov](mailto:Lantz.Tracy@epa.gov)>; Perlis, Robert <[Perlis.Robert@epa.gov](mailto:Perlis.Robert@epa.gov)>; Dunton, Cheryl <[Dunton.Cheryl@epa.gov](mailto:Dunton.Cheryl@epa.gov)>  
**Subject:** FW: GE Mosquito Final Guidance Announcement

Hello, here's FDA's listerv and Q's and A's.

The listserv has rec'd final FDA/legal approval. Let me know if we have any critical show-stoppers. It looks good to me, but you are the experts. Obviously, we'll want to use the same listserv as FDA. Let me know if we have any critical issues w/their Q's and A's as well.

Where are the EPA Q's and A's in the review chain? Will those be coming to me today? FDA would like to see those.

Thanks for all your work and expertise!

Linda

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**From:** Norris, Anne [<mailto:Anne.Norris@fda.hhs.gov>]  
**Sent:** Friday, September 29, 2017 12:23 PM  
**To:** Strauss, Linda <[Strauss.Linda@epa.gov](mailto:Strauss.Linda@epa.gov)>; StClair, Christie <[StClair.Christie@epa.gov](mailto:StClair.Christie@epa.gov)>; Valentine, Julia <[Valentine.Julia@epa.gov](mailto:Valentine.Julia@epa.gov)>; Daguillard,

Robert <[Daguillard.Robert@epa.gov](mailto:Daguillard.Robert@epa.gov)>; Putnam, Juli <[JuliAnn.Putnam@fda.hhs.gov](mailto:JuliAnn.Putnam@fda.hhs.gov)>;  
Dooren, Jennifer <[Jennifer.Dooren@fda.hhs.gov](mailto:Jennifer.Dooren@fda.hhs.gov)>  
**Cc:** Nalubola, Ritu <[Ritu.Nalubola@fda.hhs.gov](mailto:Ritu.Nalubola@fda.hhs.gov)>; Flamm, Eric  
<[Eric.Flamme@fda.hhs.gov](mailto:Eric.Flamme@fda.hhs.gov)>; Epstein, Laura <[Laura.Epstein@fda.hhs.gov](mailto:Laura.Epstein@fda.hhs.gov)>; McNally,  
Robert <[McNally.Robert@epa.gov](mailto:McNally.Robert@epa.gov)>; Milewski, Elizabeth <[Milewski.Elizabeth@epa.gov](mailto:Milewski.Elizabeth@epa.gov)>;  
Mendelsohn, Mike <[Mendelsohn.Mike@epa.gov](mailto:Mendelsohn.Mike@epa.gov)>  
**Subject:** RE: GE Mosquito Final Guidance Announcement HAPPENING THIS WEEK

Hi EPA,

Attached are our CVM Update and Responsive QAs for the GE mosquito final guidance for your awareness. They have received legal clearance from our Office of the Chief Counsel. The responsive QAs in red are new additions to our list of questions since we shared with you in January for the draft guidance, but many of the questions you saw in January now have modified responses to reflect current circumstances.

The exact timing of the announcement is still being determined and we will keep you posted. When you have developed your listserv and QAs, could you please share with us for awareness?

Please let us know if you have any questions or concerns.

Thanks!  
Anne

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**From:** Norris, Anne  
**Sent:** Thursday, September 28, 2017 2:13 PM  
**To:** 'Strauss, Linda'; 'StClair, Christie'; 'Valentine, Julia'; 'Daguillard, Robert'; Putnam, Juli  
**Cc:** Nalubola, Ritu; Flamm, Eric; Epstein, Laura; '[McNally.Robert@epa.gov](mailto:McNally.Robert@epa.gov)'; 'Milewski, Elizabeth'; 'Mendelsohn, Mike'  
**Subject:** RE: GE Mosquito Final Guidance Announcement HAPPENING THIS WEEK

Good afternoon,

We just received confirmation that this announcement will not be happening until early next week. We're awaiting precise timing, but wanted to let you know that the guidance is not going out tomorrow as originally anticipated.

Will be in touch when we know more, but hope to have the CVM Update to you very soon and the responsive QAs should follow shortly after that.

Thanks,  
Anne

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**From:** Norris, Anne  
**Sent:** Wednesday, September 27, 2017 5:46 PM  
**To:** 'Strauss, Linda'; 'StClair, Christie'; 'Valentine, Julia'; 'Daguillard, Robert'; Putnam, Juli  
**Cc:** Nalubola, Ritu; Flamm, Eric; Epstein, Laura; '[McNally.Robert@epa.gov](mailto:McNally.Robert@epa.gov)'; 'Milewski, Elizabeth'; 'Mendelsohn, Mike'  
**Subject:** RE: GE Mosquito Final Guidance Announcement HAPPENING THIS WEEK

To recap status for everyone: Linda will be in the office Thursday and Friday and she's steering the ship for EPA communications. The EPA team is working on responses to anticipated questions from press and stakeholders. FDA will share our comms tomorrow as soon as we are able.

If you have any questions or concerns, please let us know.

Thanks,  
Anne

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**From:** Norris, Anne  
**Sent:** Wednesday, September 27, 2017 5:02 PM  
**To:** 'Strauss, Linda'; 'StClair, Christie'; 'Valentine, Julia'; 'Daguillard, Robert'; Putnam, Juli  
**Cc:** Nalubola, Ritu; Flamm, Eric; Epstein, Laura; [Mcnally.Robert@epa.gov](mailto:Mcnally.Robert@epa.gov); Milewski, Elizabeth; Mendelsohn, Mike  
**Subject:** RE: GE Mosquito Final Guidance Announcement HAPPENING THIS WEEK

Looping in Bob, Elizabeth, and Mike now because I tried calling all four of the EPA communications contacts we have on this issue and can't reach anyone. Normally, I'd wait until the morning and try again, but given the time constraints, we just need to ensure that someone from EPA communications is handling this. Linda's voicemail said she's out of the office on Thursday and Friday, so hoping that if she's already signed off and taking leave, that you may be able to suggest who else we can contact.

Thanks,  
Anne

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**From:** Norris, Anne  
**Sent:** Wednesday, September 27, 2017 4:42 PM  
**To:** Strauss, Linda; StClair, Christie; Valentine, Julia; 'Daguillard, Robert'; Putnam, Juli  
**Cc:** Nalubola, Ritu; Flamm, Eric; Epstein, Laura  
**Subject:** GE Mosquito Final Guidance Announcement HAPPENING THIS WEEK  
**Importance:** High

Hi Linda,

We just learned that this final guidance is on an EXTREMELY fast trajectory and we're almost certainly going to be announcing by this Friday (9/29). Unfortunately, our communications documents are still in clearance and it would be premature to send them to you in case edits still need to be made. At this point, we should be able to share tomorrow, but it's unclear at what time.

We will share our CVM Update and Responsive QAs at the earliest point possible; however, if you wait until after you view our comms to start developing your QAs or talking points, you won't be allowing yourselves adequate time. Additionally, our responsive QAs are primarily geared toward addressing the questions that the FDA anticipates getting, which won't be very helpful for EPA's needs when it comes to questions that will be directed to EPA from media and stakeholders. Of particular sensitivity right now is the issue of mosquitoes and hurricane relief.

Given the short timeframe, we would strongly suggest that you and your team consult with the EPA policy team working on this issue to get their thoughts on what issues/questions they expect to arise and how they would advise you to handle them. My understanding is that those people are Bob McNally, Elizabeth Milewski, and Mike Mendelsohn.

As Juli had previously mentioned, some examples of the types of questions you might get could be things like:

-What further regulation will the sponsor have to go through to conduct field trials in jurisdictions within the US or to get a commercial approval for the mosquitoes? Will EPA rely on the data the sponsor already provided to the FDA? How long will the process take?

-Do you have any applications/permits/whatever the correct terminology is from Oxitec in house that you are currently reviewing?

-Does the EPA have comment on FDA's guidance? Will this delay the approval/permitting of Oxitec's GE mosquitoes to Hurricane-stricken areas?

Please keep in touch with questions and concerns – feel free to call me anytime at 240-402-0132. We'll reach out tomorrow about the status of our communications and to set up a call with you, if needed.

Thanks,  
Anne

**Anne Norris**  
*Health Communications Specialist*

Strategic Communications & Public Engagement Team  
Office of Foods and Veterinary Medicine  
U.S. Food & Drug Administration  
O: 240-402-0132  
M: 240-704-0579  
[Anne.Norris@fda.hhs.gov](mailto:Anne.Norris@fda.hhs.gov)

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